

CLAIMS

1. A pharmaceutical composition comprising, in powder form: (a) at least one active hematinic species (AHS) in a therapeutically effective total amount constituting about 30% to about 95% by weight, (b) a parenterally acceptable buffering agent in an amount of about 5% to about 60% by weight, and (c) other parenterally acceptable excipient ingredients in a total amount of zero to about 10% by weight, of the composition; said composition being reconstitutible in a parenterally acceptable liquid.

2. The composition of claim 1 wherein the AHS comprises a complex selected from the group consisting of ferric hydroxide sucrose complex, sodium ferric gluconate complex and ferric saccharate complex.

3. The composition of claim 1 wherein the complex comprises sodium ferric gluconate complex.

4. The composition of claim 1 wherein the complex comprises ferric hydroxide sucrose complex.

5. The composition of claim 1 wherein the complex comprises ferric saccharate complex.

6. The composition of claim 1 wherein the AHS is present in an amount of about 40% to about 90% by weight of the composition.

7. The composition of claim 1 wherein the AHS is present in an amount of about 50% to about 80% by weight of the composition.

8. The composition of claim 1 wherein the buffering agent is present in an amount of about 10% to about 60% by weight of the composition.

9. The composition of claim 1 wherein the buffering agent is present in an amount of about 20% to about 50% by weight of the composition.

10. The composition of claim 1 that consists essentially of the AHS and the buffering agent.

11. The composition of claim 1 wherein the buffering agent is selected from the group consisting of sodium and potassium phosphates, sodium and potassium citrates, mono-, di- and triethanolamines, tromethamine and mixtures thereof.

12. The composition of claim 1 wherein the buffering agent is selected from the group consisting of dibasic sodium and potassium phosphates and tromethamine.

13. The composition of claim 1 wherein the buffering agent is dibasic sodium phosphate.

14. The composition of claim 1 that, upon reconstitution, has a pH of about 7 to about 9.

15. An injectable composition prepared by reconstituting a composition of claim 1 in a parenterally acceptable carrier or solvent.

16. The composition of claim 15 wherein the carrier or solvent is aqueous.

17. The solution of claim 16 having pH of about 7.5 to about 8.5.

18. The solution of claim 16 wherein the aqueous carrier or solvent contains dextrose and/or sodium chloride.

19. An injectable composition prepared by reconstituting a composition of claim 3 in a parenterally acceptable carrier or solvent.

20. An injectable composition prepared by reconstituting a composition of claim 4 wherein the parenterally acceptable liquid is a carrier or solvent.

21. The solution of claim 20 wherein the carrier or solvent is aqueous.

22. The solution of claim 21 having pH of about 7.5 to about 8.5.

23. The solution of claim 21 wherein the aqueous solvent contains at least one of dextrose or sodium chloride.

24. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 1 in a sterile condition.

25. The article of manufacture of claim 24 wherein the container is a pouch or vial.

26. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 3 in a sterile condition.

27. An article of manufacture comprising a sealed container having contained therewithin a unit dosage amount of a composition of claim 4 in a sterile condition.

28. The article of manufacture of claim 26 wherein the sodium ferric gluconate complex is present in an iron dosage amount upon reconstitution of about 5 mg to about 100 mg per mL.

29. The article of manufacture of claim 27 wherein the ferric hydroxide sucrose complex is present in an iron dosage amount upon reconstitution of about 5 mg to about 100 mg per mL.

30. The article of manufacture of claim 26 wherein the container is a pouch or multicompartment vial.

31. The article of manufacture of claim 27 wherein the container is a pouch or multicompartment vial.

32. A process for preparing a reconstitutable AHS composition, the process comprising lyophilizing an aqueous composition comprising an AHS substantially free of excipients and combining said lyophilized AHS to form a mixture comprising, by weight: (a) about 30% to about 95% of said lyophilized AHS, (b) a parenterally acceptable buffering agent in an amount of about 5% to about 60%, and (c) other parenterally acceptable excipient ingredients in a total amount of zero to about 10%.

33. The process of claim 32 wherein the AHS is sodium ferric gluconate complex.

34. The process of claim 32 wherein the AHS is ferric hydroxide sucrose complex.

35. The process of claim 32 wherein the AHS is ferric saccharate complex.

36. A method of treating or preventing an iron deficiency disorder in a subject, the method comprising reconstituting a unit dosage amount of the composition of claim 1 to form a parenterally administratable composition, and administering the composition to the subject.

37. The method of claim 36 wherein the parenteral administration is by intradermal, subcutaneous, intramuscular, intravenous, intramedullary, intra-articular, intrasynovial, intraspinal, intrathecal or intracardiac injection or infusion.

38. The method of claim 36 wherein the parenteral administration is by intravenous injection or infusion.

39. The method of claim 38 wherein the composition is injected intravenously as a bolus.

4440. A method of treating or preventing an iron deficiency disorder in a subject, the method comprising reconstituting a unit dosage amount of a composition of claim 5 in a physiologically acceptable amount of a parenterally acceptable solvent liquid to form an injectable solution, and administering the solution parenterally to the subject.

4541. The method of claim 4440 wherein the parenteral administration is by intradermal, subcutaneous, intramuscular, intravenous, intramedullary, intra-articular, intrasynovial, intraspinal, intrathecal or intracardiac injection or infusion.

4642. The method of claim 4440 wherein the parenteral administration is by intravenous injection or infusion.

4743. The method of claim 4642 wherein the composition is injected intravenously as a bolus.